CLAIMS

Sub A1

1. A method of preparing homogeneous microparticles containing a pharmaceutically active substance by use of a spray freezing technique which method comprices
- atomizing into droplets a liquid medium having a minimum dry content of 15% by volume and comprising
  a) a pharmaceutically active substance,
  b) a polymer selected from the group consisting of water soluble polymers and non-water soluble polymers, said polymer being present in an amount of at least 5 per cent by weight based upon the dry content of the medium,
  c) a liquid in which the pharmaceutically active substance and polymer are suspended, dissolved or emulsified, and
  d) optionally a dispersing agent, selected from the group consisting of polymers, surfactants, other substances and mixtures thereof,
- freezing the formed droplets and
- sublimating the frozen liquid of the droplets to obtain dry, homogeneous microparticles.

2. A method according to claim 1, wherein the polymer of the liquid medium constitutes 10 weight % or more of the dry content.

3. A method according to claim 1, wherein the polymer of the liquid medium constitutes 15 weight % or more of the dry content.

4. A method according to claim 1 wherein the dry content of the liquid medium is from 15 to 60 vol %.

5. A method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a relative density of 15 to 60 %.

6. A method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a porosity of 85 down to 40 vol %.

7. A method according to claim 1 wherein the liquid medium to be spray-freezed is a suspension.

8. A method according to claim 1 wherein the liquid medium to be spray-freezed is a solution.

9. A method according to claim 1 wherein the liquid medium to be spray-freezed is an emulsion.

10. A method according to any of the preceding claims wherein the content of the pharmaceutically active substance is from 60 to 95 weight %, preferably 75 to 90 weight %, of the weight of the dried microparticles.

11. A method according to any of the preceding claims wherein the dry content of the medium is from 15 to 60 vol% and with the content of the pharmaceutically active substance being from 60 to 95 weight % of the dried microparticles.

12. A method according to any of the preceding claims wherein the polymer is selected from the group consisting of a cellulose derivative, a polysaccharide, a natural polymer, a synthetic polymer, a surfactant and mixtures thereof.

13. A method according to any of the preceding claims wherein the dispersing agent is selected from the group consisting of polymers, surfactants, other substances and mixtures thereof.

14. A method according to any of the preceding claims wherein the liquid in which the polymer is soluble is selected from the group consisting of water, tertiary butyl alcohol, cyclohexane, methylene chloride, methanol, ethanol and mixtures thereof.

Sub A1 cont.

15. A method according to any of the preceding claims wherein the cold medium is selected from the group consisting of liquid nitrogen, liquid argon, liquid oxygen or a cooled solvent well below the freezing point of the liquid in the suspension.

16. A method according to any of the preceding claims wherein the sublimation is performed by freeze-drying.

17. A method according to any of the preceding claims wherein the size distribution of the prepared microparticles are in the range from 10 to 1000 μm.

18. Microparticles when prepared according to the method of any of claims 1-17.

19. The microparticles according to claim 18 further comprising a polymeric film coating.

Sub A2

20. A method of preparing homogenous microparticles containing a pharmaceutically active substance, the particles being coated with a polymer film coating, which method comprises a method as claimed in any one of claims 1-17 followed by coating the microparticles with a polymeric film coating.

add A3